UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: EPHEDRA PRODUCTS LIABILITY LITIGATION	:	04 MD 1598 (JSR)
Pertains to:	:	06 CV 00014
Harbir Singh, *et al.* v. Herbalife International of America, Inc., *et al.*	:	

HERBALIFE INTERNATIONAL COMMUNICATIONS, INC.'S. HERBALIFE INTERNATIONAL OF AMERICA, INC.'S, AND STEVE PETERSON'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO PRECLUDE PLAINTIFFS' CASE-SPECIFIC EXPERT'S OPINIONS OR PORTIONS THEREOF

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Pursuant to Federal Rule of Civil Procedure 26(a)(2), Federal Rules of Evidence 104(a) and 702, this Court's *Daubert* Opinion (published at *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181 (S.D.N.Y. 2005)), and all relevant Case Management Orders ("CMO") in this Ephedra MDL, defendants Herbalife International Communications, Inc., Herbalife International of America, Inc., and Steve Peterson (collectively, "Herbalife") request that the Court preclude the opinions of plaintiffs' case-specific expert, Lawrence Shields, M.D., or in the alternative, preclude portions of his opinion.[1]

I.

PRELIMINARY STATEMENT

Dr. Shields' opinion should be precluded because his expert report in this case is based on grossly inaccurate facts. Dr. Shields assumed a dosage of ephedra *three times*

[1] We have assumed certain facts regarding Plaintiff's claimed injuries for the purposes of this motion only. Herbalife has and continues to dispute causation in this case.

greater than the dosage that Mr. Singh allegedly ingested. Moreover, Dr. Shields erroneously believed that Mr. Singh ingested Herbalife on the morning of his stroke. Further, Dr. Shields unreliably applied the differential diagnosis methodology to the facts of this case by not adequately considering Mr. Singh's risk factors, especially his history as a pack a day smoker. Finally, Dr. Shields' report should be stricken insofar as it sets forth impermissible and untimely general causation opinions in violation of this Court's rulings.

II.

STATEMENT OF FACTS

Plaintiff Harbir Singh is a 45 year old man, born on November 20, 1961. (Ex. A: Transcript of Deposition of Harbir Singh, dated November 8, 2006 ("Singh Dep.") at 7:23-25.) On or about May 10, 2003, Mr. Singh sustained a subarachnoid hemorrhage. (Ex. A: Singh Dep. at 357:13-15; Ex. B: Transcript of Deposition of Bruce Charles Zablow, M.D. ("Zablow Dep.") at 19:18-22.) Prior to his stroke, Mr. Singh smoked one pack of cigarettes and drank two alcoholic beverages per day for over twenty years. (Ex. A: Singh Dep. at 227:19-22, 228:24; 365:3-6.) Mr. Singh also drank up to three cups of Lipton caffeinated tea per day. *Id.* at 235:6-8.

On the morning of May 10, 2003, Mr. Singh fainted in the bathroom at home and was taken to the hospital. *Id.* at 372:4-5, 376:18-20. Shortly after Mr. Singh was admitted to the hospital, a CT scan was performed, which showed a subarachnoid hemorrhage, likely caused by a ruptured aneurysm. (Ex. B: Zablow Dep. at 19:20-21, 25:20-22.) A coiling procedure was successfully performed, stopping the flow of blood from the aneurysm. *Id.* at 27:25-28:11. During Mr. Singh's hospitalization, his treating physician, Bruce Zablow, M.D. noted the presence of dysplasia in the cervical left

internal carotid artery, which he diagnosed as "most likely fibromuscular dysplasia." *Id.* at 62:9-18. Dr. Zablow also noted that Mr. Singh showed no evidence of vasospasm prior to the stroke. *Id.* at 27:16-17.

Plaintiff claims that for one year preceding the stroke, from May 2002 until May 2003, he had ingested an Herbalife dietary supplement—Original Green—that contained ephedra. (Ex. A: Singh Dep. at 274:24-275:3, 345:9-12.) He states that he took Herbalife according to the instructions on the bottle, namely three tablets in the morning and three tablets in the evening, for a total of 42 milligrams of ephedrine alkaloids daily. (Ex. A: Singh Dep. at 346:18-19; Ex. C: Label for Herbalife Original Green, Shields Deposition Exhibit No. 11 ("Original Green Label").) The last time that Mr. Singh ingested an Herbalife ephedra-containing product was the day before the stroke, May 9, 2003. (Ex. A: Singh Dep. at 345:9-12.)

In December 2006, plaintiff provided a case-specific expert report for Lawrence W. Shields, M.D. (Ex. D: Expert Report of Lawrence W. Shields, M.D. ("Shields Report").) Herbalife deposed Dr. Shields on February 20, 2007. (Ex. E: Transcript of Deposition of Lawrence W. Shields ("Shields Dep").). Herbalife objects to Dr. Shields' report and opinion for the reasons stated herein.

III.

ARGUMENT

A. Dr. Shields' Case-Specific Causation Opinion Should Be Precluded Because It Is Not Based On Correct Facts, It Is Not Supported By The Relevant Scientific Literature, And It Is The Result Of An Unreliable Application Of Differential Diagnosis.

Simply stated, Dr. Shields got his facts wrong. Dr. Shields assumed the wrong dosage of ephedra and the wrong timing of exposure, two crucial facts that Dr. Shields

admits would change portions of his opinion. Further, his causation opinion is premised on a medical condition that Mr. Singh did not have. When presented with the correct facts, Dr. Shields proffered an explanation that is not supported by the relevant scientific literature. Finally, Dr. Shields unreliably applied the differential diagnosis methodology to the facts of the case.

Federal Rule of Evidence 702 was designed to prohibit exactly the kind of unsupported, unreliable testimony that Dr. Shields purports to offer. Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), require trial court judges to act as gatekeepers of admissible expert testimony. Under Fed. R. Evid. 702, an expert may testify only if:

> (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. These requirements are meant to ensure that "any and all scientific testimony or evidence admitted is not only relevant but reliable." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 253 (2d Cir. 2005) (quoting *Daubert*, 509 U.S. at 589). Here, Dr. Shields has relied on admittedly erroneous facts and has proffered testimony that is contradicted by both scientific literature and the evidence in the case. Such large mistakes render his opinion unreliable, and it must therefore be excluded.

1. Dr. Shields' opinion is unreliable because it is based on erroneous facts.

It is well-settled that expert testimony must be "based upon sufficient facts." Fed. R. Evid. 702. In determining whether an expert's testimony is reliable, "the district court should undertake a rigorous examination of the facts on which the expert relies." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). Where, as

here, the expert testimony is based on facts that are not supported by the record, the trial court must exercise its gate-keeping duty and exclude the testimony. *See Id.* at 266 (when "an expert opinion is based on data, a methodology or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony")*; Davidov v. Louisville Ladder Group, LLC.*, 2005 WL 486734, at *2 (S.D.N.Y., March 1, 2005) ("an expert's opinion which is not based on the evidence in the case is little more than speculation").

This Court has acknowledged the importance of correct underlying facts in two recent decisions in this Ephedra MDL. In *Starks v. Body Dynamics Inc., et al.* and *Schneider v. Rexall Sundown*, this Court excluded testimony of experts who had based their opinions on erroneous facts. (*See* Ex. F: *Schneider v. Rexall Sundown, Daubert* Hearing Transcript, dated April 2, 2007 ("Schneider Transcript"); Ex. G: *Schneider v. Rexall Sundown* Order, dated April 2, 2007 ("Schneider Order"); Ex. H: *In re Ephedra Products Liab. Litig.* Status Order, dated March 7, 2007, at 2-3 ("March 7 Order").) In *Starks*, this Court excluded the testimony of an expert who had based his opinion on the plaintiff ingesting two capsules twice per day, when the plaintiff testified that she had only taken one capsule twice per day. (Ex. H: March 7 Order at 2-3.) This Court found that the "report contain[ed] significant factual errors that render[ed] his opinions unreliable and therefore inadmissible under Rule 702 Fed. R. Evid." *Id.* at 2. Similarly, in *Schneider*, this Court held that Rule 702's requirement that expert "testimony be based upon sufficient facts or data" was not met where the expert based his opinion on the plaintiff ingesting 64 mg. of ephedra, when the plaintiff had allegedly taken only 24 mg. (Ex. F: Schneider Transcript at 55:6-19.)

a Dr. Shields' report was premised on an incorrect dosage of ephedra.[2]

In this case, even a cursory examination of the record discloses the deficiencies in Dr. Shields' understanding of the facts of Mr. Singh's injury. Dr. Shields relied on a grossly inflated dosage. Dr. Shields' report states, "[t]he product label reads: *each tablet* contains 21 mg. of concentrated ephedra extract and 3 mg. of caffeine." (Ex. D: Shields Report at 2.) (Emphasis added.) Dr. Shields' report states that Mr. Singh used three green pills, twice per day. *Id*. Thus, Dr. Shields report is premised on a dose of 6 tablets of Herbalife per day, for a daily dose of 126 milligrams of ephedrine alkaloids. In fact, the product label reads, "*three* thermojetics original green herbal tablets contain 21 mg. concentrated ephedrine group alkaloids and 3 mg. of caffeine." (Ex. C: Original Green Label.) (Emphasis added). Therefore, three tablets twice daily contain a daily dose of only 42 mg. ephedrine alkaloids, only *one-third* of the 126 mg. daily dosage assumed by Dr. Shields. This Court need not look any further for a basis to exclude Dr. Shields' opinion: as this Court has previously stated, "I don't see how we even have to get into some of the other issues, if this is a report premised on the facts that both sides agree are wrong." (Ex. I: Transcript of March 1, 2007 Ephedra MDL Hearing ("March Hearing Transcript"), at 19:13-15.)

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[2] At his deposition, Dr. Shields admits his error:

> Q. So at this point, can we agree that the statement, in terms of the dosage containing [sic] the tablet, the footnote, the asterisk on the second page of your report, it appears that may be in error, correct?
> A. Yes.

(Ex. E: Shields Dep. at 104:6-11.)

b Dr. Shields incorrectly based his opinions on Mr. Singh ingesting ephedra on the morning of the stroke.

As bad or worse than Dr. Shields' mistake in dosage is his mistake in the timing of plaintiff's alleged ephedra ingestion. Temporality of exposure is, of course, one of the critical elements of any causation opinion. Dr. Shields' December 4, 2006 report states that "Mr. Singh had taken Herbalife, an ephedra containing compound on May 10, 2003, on the day of his subarachnoid hemorrhage," even though Mr. Singh explicitly testified three weeks earlier, on November 15, 2006 that he had *not* ingested any Herbalife product on the morning of his stroke.[3] (Ex. D: Shields Report at 2, 7; Ex. A: Singh Dep. at 345:9-12.) This mistaken fact wholly undercuts Dr. Shields' opinions.

Dr. Shields' causation opinion rests on two theories, elevated systemic blood pressure and vasoconstriction. Dr. Shields summarizes his causation opinion by stating that "regional rheologic alterations, vessel wall damage and systemic blood pressure effects . . . are the prime mechanisms by which ephedra containing compounds such as Herbalife are associated with hemorrhagic strokes."[4] (Ex. D: Shields Report at 8.)

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[3] Plaintiff has testified that he did *not* ingest ephedra on the morning of the stroke:

> Q. So the day before your stroke was the last day you took Herbalife products.
> A. Yes, sir. Yes.

(Ex. A: Singh Dep. at 345:9-12.)

[4] Dr. Shields opines that "regional rheologic alterations," and "vessel wall damage" are caused by the process of vasoconstriction:

> Vasoconstriction is effected by muscular contraction in the vessel wall. Since the muscular sheeting in cerebral blood vessels is not continuous but, rather, is spiraled, a-1 stimulation produces irregular contraction patterns known as segmental constriction.. . . It is obvious that segmental constriction will produce regional alteration in the velocity, volume, pressure and direction of blood flowing through the affected vessel and that jetting of flow will occur and that turbulence will be produced.

(Ex. D: Shields Report at 8.)

Dr. Shields' opinion that ephedra caused plaintiff's stroke by increasing plaintiff's systemic blood pressure is invalidated if Mr. Singh did not ingest ephedra on the morning of the stroke. Because ephedra's alleged effect on systemic blood pressure is short lived, ephedra ingested the day before the stroke would have no lingering effect on Mr. Singh's systemic blood pressure. Dr. Shields stated that "[t]he rule for ephedrine causing sustained increase in blood pressure, assuming there's nothing that complicates the situation, is basically 5 to 6 hours is the outside limit, in terms of systemic blood pressure." (Ex. E: Shields Dep. at 84:24-85:5.) Further, Dr. Shields admits that plaintiff's systemic blood pressure would not have been elevated by ephedra at the time of the stroke if plaintiff last ingested ephedra the day before:

> Q. So if he did not take the product that day, you would not have expected it to have any effect on increasing the systemic blood pressure.
> A. Yes, in a simple situation.

Id. at 85:23-86:3. Thus, because plaintiff has clearly stated that he did not ingest ephedra on the morning of the stroke, one causation theory proffered by Dr. Shields is impossible.

The only remaining causation theory proffered by Dr. Shields is not supported by the radiographic films. If, as Dr. Shields concedes is true, ephedra did not cause an increase in plaintiff's systemic blood pressure at the time the stroke occurred, the only other proffered link between ephedra and the stroke is vasoconstriction. The flaw in this theory is that the radiographic films show no evidence of vasoconstriction. Both Mr. Singh's treating physician, Bruce Zablow, M.D., and defendant's expert stroke neurologist John Dashe, M.D.—the only two doctors involved in the case who have personally reviewed Mr. Singh's radiographic films—unequivocally state that there is no

evidence of vasoconstriction.[5] (Ex. B: Zablow Dep. at 30:11-21; Ex. J: Expert Report of John F. Dashe, M.D., dated February 26, 2007 ("Dashe Report") at 6.) Dr. Shields' report seemed to cling to one typographical error in the "impression" section of Mr. Singh's angiogram report, which states that "evidence of vasospasm was noted." (Ex. D: Shields Report at 3, Ex. B: Zablow Dep. at 31:19-24.) Dr. Shields relied on this one typo even though the note was clearly inconsistent with everything else in the medical record. (*See* Ex. K: Saint Vincents Catholic Medical Centers of New York – Manhattan Department of Radiology Report of Neuroendovascular Surgery Order No. 90007 at 2 (noting no evidence of vasospasm); Ex. L: Saint Vincents Catholic Medical Centers of New York – Manhattan Department of Radiology Report of Neuroendovascular Surgery Order No. 90008 at 2 (noting no evidence of vasospasm).) Dr. Shields now acknowledges Dr. Zablow's subsequent deposition testimony that the entry was a typographical error:

Q. [I]n the impression?
A. It says, "vasospasm."
Q. And you read Dr. Zablow's deposition yourself?
A. Yes.
Q. So you're aware he testified that was a typographical error?
A. Yes.
Q. And in fact they saw no evidence of vasospasm?
A. Yes.
Q. Do you have any reason to dispute that?
A. No, well, not that particular statement.

(Ex. E: Shields Dep. at 39:2-16.) Without any evidence of vasospasm in Mr. Singh's medical record, there is no evidence to support Dr. Shields' opinion. Therefore, Dr. Shields' speculative opinion, which is entirely unsupported by the facts of the case, must

[5] Dr. Zablow referred specifically to "vasospasm," rather than "vasoconstriction," but Dr. Shields has acknowledged that the two terms can be used interchangeably. (Ex. B: Zablow Dep., at 30:11-21; Ex. E: Shields Dep. at 86:18-24.)

be excluded. *See Macaluso v. Herman Miller, Inc.*, 2005 WL 563169, at *8 (S.D.N.Y. March 10, 2005) (finding expert opinion unreliable "because it [wa]s based on incorrect factual assumptions that render[ed] all of his subsequent conclusions purely speculative").

Additionally, Dr. Shields cannot attempt to contradict the findings of Dr. Zablow because he has not reviewed the radiographic films. In *Starks*, this Court noted that it is unscientific for an expert to opine on causation without reviewing relevant medical records:

> I can well see an expert saying, I can't give you an opinion until I get at least the basic records that I need. So if he didn't have the records at the time he was asking his opinion, he would have said, go get it or I can't give you an opinion. But instead to say, well, but even without those records, I'm going to -- I'll take alternative hypotheses. Either she had hypertension or she didn't have hypertension. Either way, it's the fault of ephedra. I mean, that doesn't sound like the way scientists are supposed to proceed.

(Ex. I: March Hearing Transcript at 34:9-18.) This situation is even worse than the *Starks* case. In *Starks*, the relevant records were unavailable. Here, the radiographic films were available and Dr. Shields could have requested them. He went to the trouble of examining the plaintiff (albeit two and a half years post-stroke), but did not take the trouble to obtain the key radiographic films of the stroke. He thus may not contravert other witnesses' impressions of those films.

Without evidence of vasospasm, there is a "gap" in the evidence and thus there is no basis for Dr. Shields' opinion. Two doctors, Dr. Zablow (who treated the plaintiff's stroke) and Dr. Dashe, have reviewed the radiographic films and both concluded that Mr. Singh showed no evidence of vasospasm. Moreover, Dr. Shields conceded that he could not dispute Dr. Zablow's finding. Notwithstanding this, Dr. Shields posits a theory

that cannot be valid without evidence of vasospasm. Rather than developing a theory based on the actual facts of the case, Dr. Shields based his opinion on the erroneous and unsupported assumption that Mr. Singh experienced vasospasm, which then caused his stroke. This opinion is not grounded in the facts of the case and Dr. Shields is in no position to make alternative factual findings without viewing the radiographic films. The opinion therefore is not reliable and must be excluded.

2. Dr. Shields' opinion must be excluded because it finds no support in the relevant scientific literature.

Even where an expert relies on correct facts, the testimony must be excluded if it is "connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). In other words, expert testimony will be prohibited where there is "a significant 'analytical gap' between the experts' opinions and the studies on which they relied in reaching their conclusions." *Amorgianos*, 303 F.3d at 270. In this case, when confronted with the errors in his report, Dr. Shields attempted to rehabilitate his opinions using conclusory statements that are not supported by the relevant scientific literature. Such unsupported opinions must be excluded.

Dr. Shields' explanation for why a two-thirds lesser dosage would not change his opinion is unsupported by the scientific literature. When asked whether his opinion as to the cause of plaintiff's stroke would change upon knowledge that plaintiff had allegedly ingested two-thirds less ephedra, Dr. Shields stated that his opinion would not change and that "any dose, in his [the plaintiff's] case, except 0, I would consider significant." (Ex. E: Shields Dep. at 102:17-18.) To support this contention, Dr. Shields stated that "there's [sic] many case reports where patients took relatively low doses of PPA. The one that comes to mind right off is the Hemorrhagic Stroke Project." (Ex. E: Shields

Dep. at 97:10-13.) This purported support is meaningless for many reasons, including that it refers to the prescription drug phenylpropanolamine, and not ephedra. Moreover, when Dr. Shields finally turned his attention to ephedra, he stated, in reference to a reanalysis of the Hemorrhagic Stroke Project data, that "the conclusion was that you needed to have 32 milligrams a day or more. That was their conclusion, of ephedra-related as opposed to pure PPA." *Id.* at 98:23-99:2. This reported "trend" actually contradicts Dr. Shields' earlier statement that *any* dose of ephedra is "significant." Dr. Shields further conceded that the Hemorrhagic Stroke Project found no statistically significant association between ephedra consumption and hemorrhagic stroke even at daily doses above 32 milligrams. (Ex. E: Shields Dep. at 99:5-8.) An opinion that is directly contradicted by the relevant scientific literature evidences a "gap too great between the science and the witness's conclusion" and the opinion must therefore be excluded. *In re Ephedra Prod. Liab. Litig.*, 393 F.Supp.2d at 189; *see General Electric*, 522 U.S. at 146 (noting that expert opinion must be excluded where there is "too great an analytical gap between the data and the opinion proffered").

3. Dr. Shields' application of differential diagnosis was unreliable.

Dr. Shields opinion is not reliable because he failed to properly apply accepted scientific methodology to the facts of the case. Dr. Shields ostensibly formulated his opinions using "differential diagnosis," "which requires listing possible causes, then eliminating all causes but one." *In re Ephedra Prod. Liab. Litig.*, 393 F.Supp.2d at 187 (internal quotations omitted). Although the Second Circuit has ruled that differential diagnosis is a reliable method that satisfies Rule 702 and *Daubert*, the method must be reliably applied to be admissible. *Id.* (noting that "differential etiology" is admissible only if "*properly* performed by a qualified physician") (emphasis added).

Dr. Shields failed to consider or appropriately account for several key pieces of evidence in his differential diagnosis. Mr. Singh exhibited at least two independent risk factors for stroke: he had smoked for over 20 years and he exhibited signs of fibromuscular dysplasia ("FMD").[6] Dr. Shields noted the presence of both of these risk factors, yet, inexplicably, he concluded that ephedra was the likely cause of Mr. Singh's stroke. (Ex. D: Shields Report at 2, 14-15.) Because Dr. Shields discounted these risk factors without providing any colorable explanation, his methodology was unreliable and his opinion should be excluded.

Smoking is well known to be the single largest risk factor for hemorrhagic strokes. (Ex. M: L. Teunissen, et al., Risk Factors for Subarachnoid Hemorrhage: A Systematic Review ("Teunissen"), Stroke 27:544-549 (1996); Ex. N: A. Qureshi et al., Risk Factors for Subarachnoid Hemorrhage, ("Qureshi"), Neurosurgery 49:607-613 (2001).) One study concluded that smokers were nearly twice as likely as non-smokers to experience a subarachnoid hemorrhage. (Ex. M: Teunissen at 544.) Even Dr. Shields acknowledged that cigarette smoking "weakened the wall of the aneurysm" and "was a predisposing risk factor [for Mr. Singh's stroke]" (Ex. E: Shields Dep. at 161:16-17; Ex. D: Shields Report at 15.) Despite this, Dr. Shields concluded "with a reasonable degree of medical certainty" that ephedra was the cause of Mr. Singh's stroke. (Ex. D: Shields Report at 14-15.)

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[6] Two other significant risk factors for subarachnoid hemorrhage are hypertension and alcohol abuse. (Ex. M: L. Teunissen, et al., Risk Factors for Subarachnoid Hemorrhage: A Systematic Review, Stroke 27:544-549 (1996).) Mr. Singh has few, if any, blood pressure readings in his medical history to use to determine whether he had a history of hypertension. (Ex. E: Shields Dep. at 69:10-14.) In addition, Mr. Singh has testified that prior to his stroke, he regularly consumed up to two alcoholic beverages per day. (Ex. A: Singh Dep. at 365:3-6.)

In concluding that ephedra caused Mr. Singh's stroke, Dr. Shields impermissibly ruled out smoking from his differential diagnosis without providing a plausible explanation. The only explanation that Dr. Shields posited is undermined by the scientific literature. Dr. Shields postulated that smoking did not cause Mr. Singh's stroke because, although Mr. Singh was a smoker, Mr. Singh had not smoked on the morning of the stroke. (Ex. E: Shields Dep. at 108:23-109:3.)[7] Dr. Shields provided no support for his theory and, in fact, the theory is undermined by at least two studies. One study concluded that even if a smoker quits smoking, the risk of subarachnoid hemorrhage remains elevated. (Ex. N: Qureshi at 607.) If risk of hemorrhagic stroke is not lowered when a person quits smoking altogether, it cannot possibly be lowered just because a current smoker did not smoke on the morning of the stroke. Similarly, if, as Dr. Shields posits, smoking causes a short-term increase in the risk of hemorrhagic stroke, then even transient smoking would increase risk in the short-term. However, there is no association between transient heavy smoking and risk of subarachnoid hemorrhage. (Ex. O: C. Anderson, et al., Triggers of Subarachnoid Hemorrhage, Role of Physical Exertion, Smoking, and Alcohol in the Australasian Cooperative Research on Subarachnoid Hemorrhage Study ("Anderson"), Stroke 34:1771-1776 (2003).) The literature therefore indicates that smoking is a major risk factor for hemorrhagic stroke even if the patient did not smoke on the day of the stroke, which directly undermines Dr. Shields' theory.

[7] Dr. Shields theorized that "the long-term increase in smoking risk for patients who have subarachnoid hemorrhage is actually two and a half to three times people who don't smoke who have aneurysms. If you smoke on the day, there's a nine times greater chance . . ." (Ex. E: Shields Dep. at 107:20-25.) So, even by Dr. Shields' admission, smoking increased Mr. Singh's risk of stroke two to threefold even if he had not yet smoked that day.

Dr. Shields' reliance on his own conclusory, unsupported theory cannot form the basis for a reliable differential diagnosis.

Similarly, Dr. Shields failed to rule out FMD as a cause of plaintiff's stroke. Mr. Singh displayed evidence of FMD, another possible risk factor for stroke. (Ex. B: Zablow Dep. at 62:9-15; Ex. P: H. Cloft, et al., Prevalence of cerebral aneurysms in patients with fibromuscular dysplasia: a reassessment, J. Neurosurgery 88:436-440 (1998).) Dr. Shields does not argue that FMD is not a risk factor for stroke, thereby implicitly conceding that FMD is a risk factor. Instead, he questions whether Mr. Singh in fact had FMD. However, as discussed above, he is not in a position to make this determination without reviewing the radiographic films. Dr. Shields could have reviewed the films and formulated a conclusion based on those films, but he chose not to do so. Instead Dr. Shields relied on his own version of the facts without regard for whether his version bore any relationship to the actual evidence in this case. Dr. Shields' failure to rule out FMD in his differential diagnosis further evidences an unreliable application of differential diagnosis to the facts of the case.

Rather than conduct a meaningful differential diagnosis, Dr. Shields conclusorily stated, "[t]hat ephedra containing products such as Herbalife have been related to aneurysmal rupture and consequent subarachnoid hemorrhage is well demonstrated in the medical literature." (Ex. D: Shields Report at 14.) Dr. Shields appears to allow this one conclusory statement to override a medical history containing two independent risk factors for stroke. Such a one-sided purported "differential diagnosis" is unreliable and must be excluded. *See McClain v. Metabolife Int'l Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("[a]n expert does not establish the reliability of his techniques or the validity of

his conclusions simply by claiming that he performed a differential diagnosis on the patient"); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) (holding that an expert's use of "boilerplate objections" rather than a meaningful differential diagnosis is "not a reliable basis for expert testimony").

B. The Court Should Preclude Portions Of Dr. Shields' Opinion For Violating The Court's *Daubert* Opinion And Case Management Orders By Opining As To General Causation

This Court should strike those portions of Dr. Shields' expert report that are directed to general, rather than specific, causation. Under this Court's Case Management Orders, all ephedra plaintiffs were required to disclose "generic experts" with regard to ephedra's potential to cause cardiac and other injuries before August 13, 2004. (Ex. Q: Stipulation and Order Amending Case Management Orders Nos. 1 and 2, so ordered June 21, 2004) (amending CMO 1, ¶ XIV(B)(1)) ("Stipulation and Order").)

In Case Management Order 1, ¶ XIVA, this Court stated:

> Every party . . . that intends to offer expert testimony in support of such claim . . . must make the disclosures required by Fed. R. Civ. P. 26(a)(2) in accordance with the requirements of this provision. No expert testimony (whether it is designated as "rebuttal" or otherwise) will be permitted by other experts or beyond the scope of the opinions covered by the aforementioned disclosures except on prior express permission by the Court, application for which must be made no later than 10 days after the date for disclosure of expert witnesses by party-opponents as set forth infra.

(Ex. R: CMO 1.)

Moreover, the Court has already squarely addressed this issue in *Smoot v. AST Sports Science, Inc.*), where it held:

> Case-specific experts may 'connect the dots' between ephedra and the particular plaintiff's injury by quoting, paraphrasing or incorporating by reference the court-approved reports of the PCC's experts. They may not offer new or additional testimony about the

> inherent properties of ephedra, such as its alleged capacity to cause injury.

(Ex. S: *Smoot v. AST Sports Science, Inc.*, No. 04 M.D. 1598, No. 04 Civ. 5482, slip op. at 2 (S.D.N.Y. Feb 28, 2006) ("Smoot Order).) The Court made clear that case-specific experts will not be permitted to opine "about the inherent properties of ephedra, a subject which the Court assigned exclusively to the PCC's generic experts." (Ex. S: Smoot Order at 3.)

This Court also gave guidance as to the use of general and specific causation in its *Daubert* opinion where it explained that a "general causation" opinion focuses on the question of whether "ephedra cause[s] a given kind of injury," while the "specific causation" inquiry focuses on whether "a given person's use of ephedra cause[d] his particular injury." *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d at 186. The Court has also previously "denied the PCC's request for an order permitting case-specific experts in MDL cases to testify at trial on the general-causation issues that were assigned to the PCC's "generic experts" and were the subject of the Court's *Daubert* opinion and order." (Ex. T: CMO 18, ¶ 8.)

The vast majority of Dr. Shields' report consists of general causation opinions, which he is prohibited from giving by this court's Case Management Orders. The "Analysis" section of his report, from page seven through page ten, is comprised solely of general causation opinions and Herbalife asks that the section be stricken in its entirety. Below are some more flagrant examples of general causation opinions:

> Ephedrine, phenylpropanolamine and others in the ephedra species group are sympathomimetic amines that have the capacity to, and do, directly and indirectly stimulate the α-1 receptor, producing vasoconstriction (narrowing of blood vessels).

* * *

> All the factors above outlining the mechanisms and physical characteristics underlying ephedra containing products such as Herbalife's association with intracranial hemorrhage apply whether the vessels so exposed are of anomalous structure or not. The presence of the most typical anomalies, aneurysms (as in Mr. Singh's case) and arteriovenous malformations, simply render these structures more vulnerable to the deleterious effects of the pharmacologic mix contained in Herbalife.

* * *

> Cerebral Aneurysm/Cerebral Aneurysmal Rupture

* * *

> The usual causes of acute systemic blood pressure elevation and/or regional flow surges are . . . pharmacologic agents such as ephedra species. . ..

(Ex. D: Shields Report at 8-10.) In addition, Dr. Shields proffers unacceptable general causation opinions in his purported "differential diagnosis," where he states:

> That ephedra containing products such as Herbalife have been related to aneurysmal rupture and consequent subarachnoid hemorrhage is well demonstrated in the medical literature.

(Ex. D: Shields report at 14.)

Dr. Shields is providing general causation testimony in these portions of his report in contravention of this Court's clear mandate that a case-specific expert may not provide such testimony. He did not connect the dots between plaintiff Harbir Singh's alleged use of ephedra and the stroke, but rather discussed generally the properties of ephedra, the very subject prohibited by this Court in *Smoot*. (Ex. S: Smoot Order at 3.) Because Dr. Shields' "Analysis" section proffers only impermissible general causation opinions, the section should be stricken in its entirety.

Moreover, without the "Analysis" section, Dr. Shields provides no link between Mr. Singh's alleged ephedra ingestion and his stroke. Without the impermissible general causation opinions of the Analysis section, all that is left of Dr. Shields' report is a regurgitation of Mr. Singh's medical records and a basic summary of an examination. There is absolutely nothing linking the general causation opinions of the generic experts to Mr. Singh's symptoms. Without such a link, Dr. Shields' opinion should be stricken.

IV.

CONCLUSION

Dr. Shields' opinion should be precluded because it is based on entirely incorrect facts, premised on a medical condition not found to exist, and not supported by the scientific literature. In addition, Dr. Shields chose not to review or request the radiological films. Further, Dr. Shields does not reliably apply his differential diagnosis to the facts of this case. Finally, Dr. Shields' report rests solely on impermissible general causation opinions and does not link those opinions to Mr. Singh's injuries. For these reasons, Dr. Shields' testimony must be excluded.

WHEREFORE, defendants Herbalife International Communications, Inc., Herbalife International of America, Inc., and Steve Peterson respectfully request an order precluding the expert opinion of plaintiff's case specific expert, Dr. Shields, along with such other and further relief as the Court deems just and proper.

Dated: May 14, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2007, I caused a true and correct copy of the foregoing HERBALIFE INTERNATIONAL COMMUNICATIONS, INC.'S HERBALIFE INTERNATIONAL OF AMERICA, INC.'S AND STEVE PETERSON'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO PRECLUDE PLAINTIFFS' CASE-SPECIFIC EXPERT'S OPINIONS OR PORTIONS THEREOF to be served via E-Mail, via Federal Express overnight mail, and via the Electronic Case Filing System, upon:

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